Essai Clinique

Généré le 24 avr. 2024 à partir de

Titre	Étude ouverte multicentrique portant sur l'augmentation et l'expansion de la dose visant à évaluer l'innocuité, la tolérabilité, la dosimétrie et l'efficacité préliminaire du radioligand CAM-H2 dirigé contre le gène HER2 chez les patients atteints d'un cancer du sein, de l'estomac ou de la jonction gastro-œsophagienne HER2 positif avancé ou métastatique
Protocole ID	CAMH2-1001
ClinicalTrials.gov ID	NCT04467515
Type(s) de cancer	Estomac Sein
Phase	Phase I-II
Type étude	Clinique
Médicament	CAM-H2 Radioligand
Institution	CENTRE UNIVERSITAIRE DE SANTE MCGILL SITE GLEN 1001 boul. Décarie , Montréal, QC, H4A 3J1
Ville	
Investigateur principal	Dr Catalin Mihalcioiu
Coordonnateur	Aboudrazako Dembele 514-934-1934 poste 37493
Statut	Actif en recrutement
But étude	This is a Phase 1/2 multi-center, open label, dose escalation and dose expansion study to evaluate safety, tolerability, dosimetry, pharmacodynamics (PD), and efficacy of the targeted radionuclide therapeutic CAM-H2 in patients with progressive, advanced/metastatic HER2-positive breast, gastric, and GEJ cancer with disease progression following anti-HER2 standard of care treatment. The study duration for each phase will be up to 18 months. The study is comprised of a Treatment Period, consisting of a maximum of 2 cycles (12 weeks per cycle) of study drug, and a 12-month Long-Term Follow-Up Period.
Critères d'éligibilité	• Informed consent form signed voluntarily before any study-related procedure is performed,indicating that the patient understands the purpose of, and procedures required for, the study and is willing to participate in the study. • Males and females ≥ 18 years of age. • Eastern Cooperative Oncology Group performance status of 0 to 1. • HER2-positive locally advanced or metastatic breast cancer refractory to standard cancer treatment or HER2-positive locally advanced or metastatic gastric or GEJ cancer, refractory to standard cancer treatment. • Patients should have a minimum of 1 measurable lesion on computed tomography (CT) or magnetic resonance imaging (MRI) as defined by RECIST version 1.1 within 4 weeks of the first dose of the study drug (Day 1). The lesion has to be a new lesion or progression of an existing lesion under the current therapy. • Patients with brain metastases should have a minimum of 1 measurable lesion on MRI as defined by RANO-BM within 4 weeks of the first dose of the study drug (Day 1). The lesion has to be a new lesion or progression of an existing lesion under the current therapy. • Any previous anti-HER2 treatment for advanced or metastatic disease is allowed. Patients with breast cancer should have had at least 2 previous systemic anticancer treatments for recurrent, locally advanced or metastatic cancer. Patients with gastric cancer or GEJ cancer should have had at least 1 previous anti-HER2 treatment. • Life expectancy > 6 months. • Adequate organ function, determined by the following laboratory tests performed within 21 days

	before screening: • Adequate kidney function with an estimated creatinine clearance of > 60 mL/min (Chronic Kidney Disease Epidemiology Collaboration formula). • Adequate hepatic function defined as an alanine aminotransferase (ALT) and aspartate aminotransferase (AST) < 2.5 the upper limit of normal (ULN), or < 5 ULN in patients with liver metastases, and total bilirubin < 2 x ULN. • Baseline left ventricular ejection fraction ≥ 50% as measured by echocardiography or multigated acquisition scan. • Absence of any psychological, family, sociological, or geographical circumstance that could potentially represent an obstacle to compliance with the study protocol and the follow-up schedule, as determined by the Investigator. These circumstances will be discussed with the patient before enrollment in the study. • Female patients of childbearing potential (ie, ovulating, premenopausal, and not surgically sterile) must have a negative serum pregnancy test within 7 days prior to administration of study drug. Patients and their partners of childbearing potential must be willing to use 2 methods of contraception, 1 of which must be a barrier method, for the duration of the study and should be maintained until 6 months after study drug administration. Medically acceptable barrier methods include condom with spermicide or diaphragm with spermicide. Medically acceptable non-barrier contraceptive methods include intrauterine devices or hormonal contraceptives (oral, implant, injection, ring, or patch).
Critères d'exclusion	• Presence of frank leptomeningeal disease as a unique central nervous system feature or in association with brain parenchymal measurable lesion(s). • Symptomatic brain metastases. Note: Patients with asymptomatic treated and untreated brain metastases are eligible. • Previous local therapy for brain metastases, such as neurosurgery, stereotactic radiotherapy, or whole brain radiotherapy, administered within 6 weeks prior to administration of CAM-H2.Note: Previous therapy for brain metastases administered at least 6 weeks prior to CAM-H2 administration will be permitted. • For patients with brain metastases, any increase in corticosteroid dose during the week prior to enrollment.Note: Corticosteroid treatment in a stable dose or decreasing dose for at least 4 weeks prior to enrollment is allowed. • Uncontrolled intercurrent illness including, but not limited to, ongoing or active infection requiring parenteral antibiotics or psychiatric illness/social situations that would limit compliance with study requirements. • Uncontrolled thyroid disease, defined as free triiodothyronine (T3) and free thyroxine (T4) > 3 x ULN at screening. • Uncontrolled diabetes defined as a fasting serum glucose > 2 x ULN or glycated hemoglobin levels > 8.5% at screening. • Gastrointestinal (GI) tract disease resulting in an inability to take oral medication, malabsorption syndrome, a requirement for intravenous (IV) alimentation, prior surgical procedures affecting absorption, or uncontrolled inflammatory GI disease (eg, Crohn's, ulcerative colitis). • Current active hepatic or biliary disease (exception of patients with Gilbert's syndrome, asymptomatic gallstones, liver metastases, or stable chronic liver disease per Investigator assessment). • Ongoing peripheral neuropathy of Grade > 2 according to the Common Terminology Criteria for Adverse Events (CTCAE) version 5.0. • Severe and/or uncontrolled medical conditions or other conditions that could affect participation in the study such as: • Symptomatic congestive heart failure of New York Heart Association Class III or IV. • Unstable angina pectoris, symptomatic congestive heart failure, myocardial infarction within 6 months of start of study drug, serious uncontrolled cardiac arrhythmia, or any other clinically significant cardiac disease. • Liver disease, including cirrhosis and severe hepatic impairment. • Active (acute or chronic) or uncontrolled severe infections. • Known history of HIV, hepatitis B, or active hepatitis C virus at screening. • Prior investigational anticancer therapy within 4 weeks prior to CAM-H2 administration. • Patients who have had a major surgery or significant traumatic injury within 4 weeks of start of study drug, who have not recovered from side effects of any major surgery (defined as requiring general anesthesia), or have a major surgery planned during the course of the study. • Other malignancies within the past 3 years except for adequately treated carcinoma of cervix or basal or squamous cell carcinomas of the skin or stage I uterine cancer. • Radiation therapy for metastatic disease foci outside the brain, administered within 3 weeks before study enrollment. • Known hypersensitivity to any of the study drugs, including inactive ingredients, including iodine allergy. • History of significant comorbidities that, in the Investigator's judgement, may interfere with study conduct, response assessment, or informed consent. • Unable or unwilling to complete the study procedures. • Patients that cannot be hospitalized in a radionuclide therapy room. • Patients that are unable to comply with thyroid protective pre-medication. • Patients in whom bladder catheterization cannot be performed, or in patients who are unwilling to be catheterized if necessary. • Patients with contraindications for undergoing MRI or CT, including for receiving contrast agents. • Patient is the Investigator or sub-Investigator, research assistant, pharmacist, study coordinator,

	or other staff or relative thereof, who is directly involved in the conduct of the study.